



**UNITED STATES DEPARTMENT OF COMMERCE
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SERIAL NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTORNEY DOCKET NO.
08/803,458	02/20/97	MATSUMOTO	T 6208.570

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HM31/0511

EXAMINER	
SAUCIER, S	
ART UNIT	PAPER NUMBER
1651	

DATE MAILED: 05/11/98

Please find below a communication from the EXAMINER in charge of this application.

Commissioner of Patents

Office Action Summary

Application No.

08/803,458

Applicant(s)

Matsumoto

Examiner

Sandra Saucier

Group Art Unit

1651



☒ Responsive to communication(s) filed on Feb 26, 1998

☒ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 1-9 is/are pending in the application.

Of the above, claim(s) 3-5 and 7-9 is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 1, 2, and 6 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☒ None of the CERTIFIED copies of the priority documents have been

☒ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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DETAILED ACTION

Claims 1-9 are pending. Claims 1, 2 and 6 are considered on the merits. Claims 3-5, 7-9 are withdrawn from consideration as being drawn to a non-elected invention.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 112

Claims 1, 2 and 6 remain rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The examples use the two solutions, RLB and BELMAR produced by the Harajuku Clinic. It is not clear whether or not these solutions are commercially available. Nor is there any description given of the components of these solutions. If the solutions are commercially available, catalog pages describing the solutions would provide evidence of enablement. The specification only recites the use of hypotonic or hypertonic solutions and does not give any values of osmolality, or the components of these solutions. The method is an empirical one and involves the production of uncharacterized cell fractions, which are produced only with RLB and BELMAR solutions. Thus, one of skill in the art would not have sufficient guidance to practice the invention as claimed.

Response to Arguments

Applicant's arguments filed 2/26/98 have been fully considered but they are not persuasive.

Applicants argue that the specification discloses that the hypotonic solution is formed from a saponin solution. However, no concentration of saponin is given, no tonicity values are given, no disclosure is given in the examples of the components of the solutions used which are critical to obtain the uncharacterized fractions.

Further, applicants state that they have identified the solutions by a brand name and source, thus they have complied with the best mode requirements. Applicants have not complied because it is not certain whether or not these solutions are commercially available. The solutions

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have not been taught so that one of skill in the art could replicate them, nor have they been shown to be commercially available. The rejection stands.

Claim Rejections - 35 USC § 102/103

Claim 6 remains rejected under 35 U.S.C. 102 (b) or in the alternative under 35 U.S.C. 103(a) as being unpatentable over Miyalaki et al. [U] or Gabay et al. [V] or Pereira et al. [X] or US 5459235 [A].

Miyalaki et al. is a review which discloses blood cell carried proteins which have antimicrobial activity. For example, defensins, cathepsin G, calprotectin are all synthesized by neutrophils.

Gabay et al. is a review which discloses blood cell carried proteins which have antimicrobial activity. For example, defensins, serprocidins and others.

Pereira et al. disclose CAP57 and CAP37, synthesized by leukocytes, which has antibiotic activity.

US 5459235 discloses that blood cells contain antimicrobial proteins, such as defensins.

It is reasonable to assume that the treatment of the blood cells in the claimed method would rupture them or cause leakage of the various intracellular proteins known to have antibiotic activity. Thus, the composition as claimed in a product by process claim, is either the same or so close as to be patentably indistinct from or obvious over the disclosed compositions.

Mere discovery of a new process to make an old material does not confer patentability on the old material.

The Patent and Trademark Office is not equipped to conduct experimentation in order to determine whether or not applicants' composition differs and, if so, to what extent from the composition discussed in the references. Accordingly, it has been established that the prior art composition, which has the same origin and shares the antibiotic property of the claimed composition demonstrates a reasonable probability that it is either identical or sufficiently similar that whatever differences exist are not patentably significant. Therefore, the burden of establishing novelty or unobviousness by objective evidence is shifted to applicants.

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Response to Arguments

Applicants argue that none of the references teaches or suggest fractionation of blood into upper, intermediate and lower layers with the upper layer then being treated to create an antibacterial composition. This is true. However, a composition which is claimed in a product by process manner can be considered to be the same as a composition made by another process in the absence of evidence. The uncharacterized composition of the claims is considered to have the same active component(s) as the compositions disclosed by the references in the absence of evidence to the contrary. Merely producing a crude fraction which contains a known antibacterial component does not confer patentability on the crude fraction.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sandra Saucier whose telephone number is (703) 308-1084. Status inquiries may be directed to the Service Desk at (703) 308-0196. The numbers of the Fax Center for the faxing of papers are (703) 305-4242 and (703) 305-3014.



Sandra Saucier
Primary Examiner
Art Unit 1651
May 7, 1998